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(54) **Implantable plastic moulding**

(57) An implantable, substantially oval, lens-shaped body of a tissue-compatible plastic material which is resistant to wetting by aqueous media and which is substantially defined by two curved surfaces, one curved surface being concave, and approximately cylindrical, the curvature of which matches that of a human thorax in the breast region, and the other being convex and approximately spherical, the radius of which is less than the radius of curvature of the said cylindrical surface. The body may be used as a filler for a breast prosethesis following removal of the breast until the operation area has fully healed.

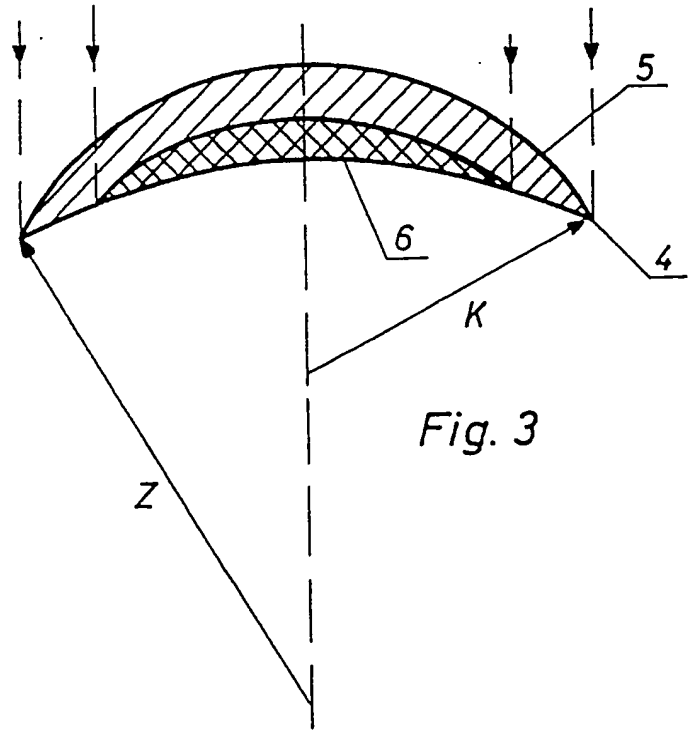

Fig. 3

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Fig. 1

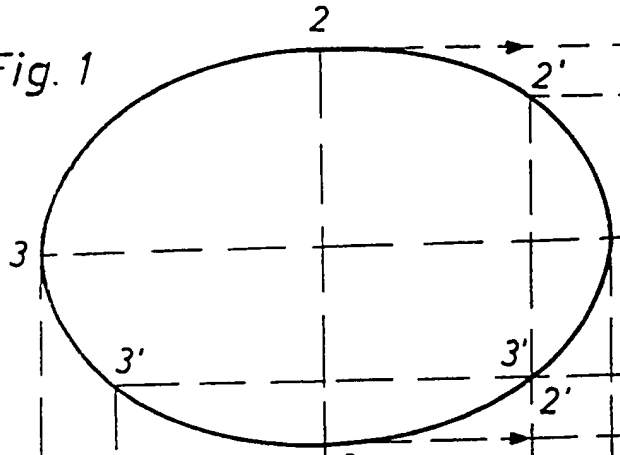
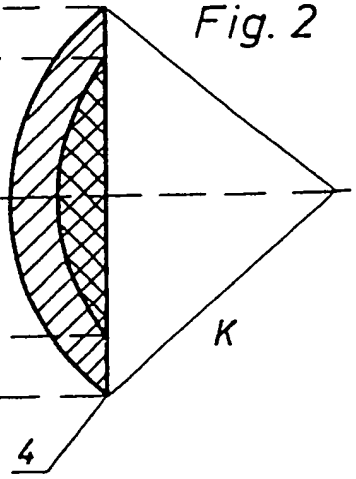


Fig. 2



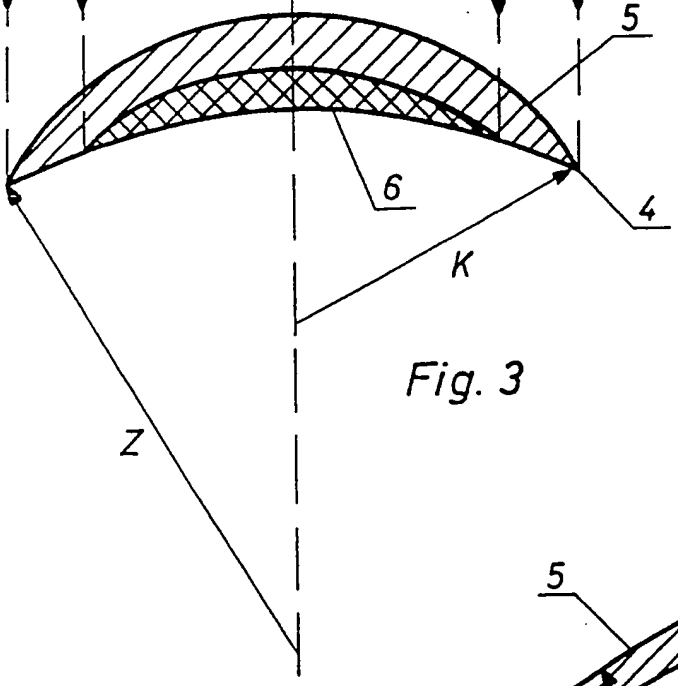


Fig. 3

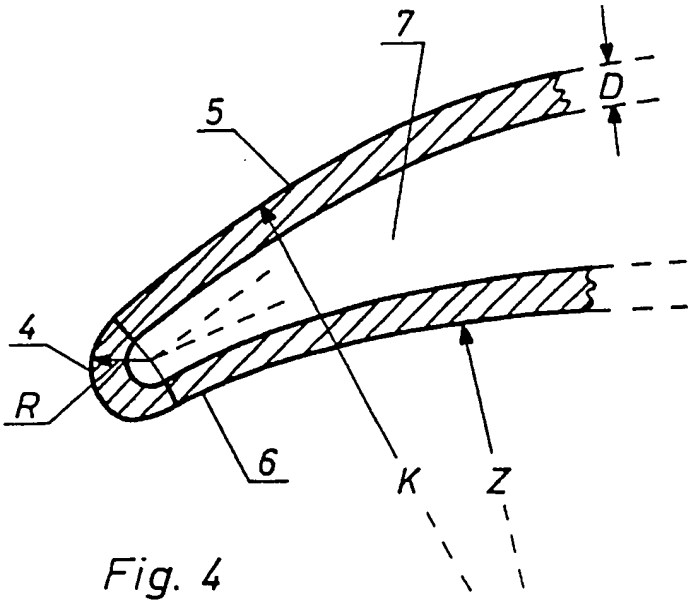


Fig. 4

SPECIFICATION

Implantable plastic insert

This invention relates to an implantable plastic insert, more particularly it relates to a lens-shaped plastic body which can be used in surgery as a temporary filler for a breast prosthesis after removal of a mammary gland, especially following breast cancer operations.

After a mastectomy, a breast may be reconstructed by inserting into the pocket of skin that remains a prosthesis comprising a silicon gel contained in a foil bag. As a result of scarring processes - the so-called capsular fibrosis-spherical deformation of the prosthesis frequently occurs. To remedy this disadvantage, Gianella ("Breast cancer and breast reconstruction"; Internat. Symposium Munich, Publisher Heinz Bohmert, Georg Thieme Verlag, Stuttgart-New York, 1982, pafes 183 - 187) and Audretsch (loc.cit. pages 92 - 100) have proposed to use first, after the operation, a filler and to exchange this for the final prosthesis in a follow-up operation only after the area of th operation has healed.

Gianella uses as a filler a foil bag which is filled with liquid, the volume of which, once implanted, can be varied. Audretsch uses as a filler a flat circular disc made of flexible silicon material. Neither type of filler prevents strong scar tissue from arising, and this can subsequently result in disturbing capular fibrosis. Moreover, shrinkage of the skin and ligature of the inner surface of the wound to plastic material surrounding the silicon may also occur.

There is therefore a need to provide an implantable filler which does not have, or has to a lesser extent the disadvantages of known fillers described above.

According to the invention, therefore we provide an implantable, substantially oval, lens-shaped body of a tissue-compatible plastic material which is resistant to wetting by aqueous media and which is substantially defined by two curved surfaces, one curved surface being concave and approximately cylindrical, the curvature of which matches that of a human thorax in the breast region, and the other being convex and approximately spherical, the radius of which is less than the radius of curvature of the said cylindrical surface.

The plastic material used and its surface quality are of great importance for the properties of the implantable body. Histological evidence indicates that the formation of widespread scar tissue is prevented during healing of the operation area if the plastic material is resistant to wetting by the aqueous media. Since roughness promotes wettability, the plastic surface should be as smooth and as pore-free as possible. Furthermore, the material should not swell or soften in an aqueous medium. Water absorption should remain within such limits that the wettability is not influenced to any substantial extent and the mechanical properties remain largely unchanged.

The wettability of a plastic can be tested according to DIN 53900 by measuring the edge angle of a water drop resting on it. The plastics suitable for the invention show edge angles of at least 50°, especially 60° to 75°.

The body as a whole will be sufficiently rigid or dimensionally stable, such that it is not visibly deformed in any position under its own weight. The body may be deformed elastically under the effect of forces which can act on the human body without damage thereto. In particular the radius of curvature of the cylindrical surface can vary, but such deformations must disappear and the original shape be restored when the deforming force ceases.

The plastic material must be tissue-compatible in every respect and should not emit any toxic constituents. Plastics of this type are known. These include acrylic glass, in particular, the polymers of methyl methacrylate and copolymers consisting of a predominant proportion of this ester together with other comonomers, especially with esters of acrylic acid or higher esters of methacrylic acid. To achieve greater flexibility, acrylic plastics consisting of a predominant proportion of acrylates and higher methacrylates, if appropriate together with homopolar or heteropolar cross-linking monomers, can also be used. Acrylic glass is particularly useful amongst the various types of plastics due to its high tissue compatibility.

The shape of the body is as important for the desired effect as the quality of the plastic material, in order to allow undisturbed healing of the operation area. It is essential, for this purpose, that the wound tissue should reheal into its original natural position over the body. The shape of the body may be matched to the mammary gland removed, so that there remain in the region of the wound no cavities which could fill with excess scar tissue during the healing process. After the wound has healed, a skin incision, which causes only a negligibly small wound in comparison with the preceding mastectomy, allows the removal of the filler and its replacement by the permanent prosthesis, e.g. consisting of a silicon gel encased in foil. This fills the same space as the original filler and thus does not give rise to any further skin growth or scar tissue development. During the healing of the inner wound surfaces, a small cavity matching the shape of the filler that has not been irritated and which corresponds to the volume of the previous mammary gland is obtained.

The shape of the plastic body should desirably correspond to the natural shape of the breast when the patient is lying on her back, and should fit closely over the thorax from which the breast has been removed

The form as described above does not need to be adhered to exactly, but allows variations as long as they are not contrary to the medical purpose. Consequently, the surfaces mentioned need correspond only approximately to a spherical and cylindrical surface.

The invention will now be more particularly described with reference to the accompanying drawings, which are by way of Example only, and in which;

Figure 1 shows a plan view of a body of the invention.

Figures 2 and *3* show by hatching the sectional

surfaces along the lines 2-2 and 3-3 in Figure 1. Further sectional surfaces along the lines 2'-2' and 3'-3' respectively are shown with double hatching in Figures 2 and 3.

Figure 4 illustrates a cross-section through a preferred embodiment of the invention in a method of representation corresponding to Figure 3.

In Figure 1 to 3, the radius Z of the cylindrical surface corresponds to the radius of curvature of the thorax in the region of the breast, including the musculature located above the ribs. The radius Z should be individually determined according to the thorax of the patient to be treated and should take into account possible variations from the circular form.

The radius K of the spherical surface is also preferably adapted to the anatomical dimensions of the patient.

The edge of intersection (4) of the spherical surface (5) with the cylindrical surface (6) represents in geometrical terms a sharp cutting edge which, in the implanted state, would cause tissue irritation and would therefore be inappropriate. Consequently, it is preferred that the spherical surface (5) be allowed to merge into the cylindrical surface (6) with a radius of curvature R of approximately 0.5 to 5 mm.

According to an embodiment of the invention in Figure 4 the body is designed as a hollow body with at least one cavity (7) and with a wall thickness D of the plastic shell of approximately 1 to 5 mm. This construction allows the body to be simply produced from plate-shaped acrylic glass of a thickness D and also gives the body substantially less weight than a solid body. The weight can be below 200 g, and is preferably below 100 g. In a typical example the weight is 50 g and the wall thickness is 1.5 mm.

To produce the body, the spherical surface (5) and the cylindrical surface (6) are each formed separately from plane plastic plate material in a way known *per se*. The blanks are then joined together by means of a suitable adhesive technique, with their oval base surfaces coinciding with one another, and the edges are rounded and polished. It is preferable to make a small bore in one of the initial surfaces, in order to make it possible, if necessary to remove gaseous constituents of the adhesive which have penetrated into the cavity. The bore is then closed.

CLAIMS

1. An implantable, substantially oval, lens-shaped body of a tissue-compatible plastic material which is resistant to wetting by aqueous media and which is substantially defined by two curved surfaces, one curved surface being concave, and approximately cylindrical, the curvature of which matches that of a human thorax in the breast region, and the other being convex and approximately spherical, the radius of which is less than the radius of curvature of the said cylindrical surface.

2. A body as claimed in claim 1 formed from an acrylic plastic consisting of a predominant proportion of acrylates and higher methacrylates together with other comonomers and also containing, if desired homopolar or heteropolar cross linking monomers.

3. A body as claimed in claim 1 or claim 2, wherein the cylindrical surface and the spherical surface merge into one another with a radius of curvature of between 0.5 and 5mm.

4. A body as claimed in any of claims 1 to 3, wherein the spherical surface has a radius of from 4 to 10cm and the cylindrical surface has a radius of curvature of from 8 to 20cm.

5. A body as claimed in any of claims 1 to 4, wherein the volume is from 100 to 300cm^3.

6. A body as claimed in any of claims 1 to 5, which is formed from acrylic glass and contains a hollow portion.

7. A body substantially as hereinbefore described and with reference to the accompanying drawings.

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